United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR ITALY

SEPTEMBER 9 THROUGH SEPTEMBER 30, 2000

July 16, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Italy's meat inspection system from September 9 through September 30, 2000. Nine of the 120 establishments certified to export meat to the United States (US) were audited. Seven of these were slaughter establishments; the other two were conducting processing operations.

The last audit of the Italian meat inspection system was conducted in January 1999. Twenty-six establishments were audited: twenty-one were acceptable, and five were evaluated as acceptable/re-review. The five establishments evaluated as acceptable/re-review were included for on-site reviews in this current audit.

The major concerns from the previous audit were the following:

1. In seven of 26 establishments, periodic supervisory visits were not performed monthly. *This is a repeat deficiency from the audit of February 1998.*

2. In five of 26 establishments, SSOP implementation problems were noted. *This is also a repeat deficiency from the audit of February 1998.*

3. In eight of 26 establishments, contamination problems were noted. *This is also a repeat deficiency from the audit of February 1998.*

4. No species verification testing program. Establishments visited were conducting operations involving only carcasses, primal parts, and hams therefore, species verification testing was not required.

5. No boneless meat re-inspection program. The establishments audited were conducting operations that did not require a boneless meat re-inspection program.

Italy only exports processed pork products to the US. Restrictions are placed on Italian fresh pork due to the presence of hog cholera and swine fever. During the period of January 1 to July 31, 2000, certified Italian establishments exported approximately 2,227,378 pounds of processed pork products to the US. Port-of-entry rejections were for contamination (0.72%) and transportation damage (0.002%).

PROTOCOL

Inspection Program Audits: This on-site audit was conducted in four parts. One part involved visits with Italian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records from 11 establishments at the Italian meat inspection headquarters. The third part was conducted by on-site visits to nine establishments. The fourth was a visit to the microbiology laboratory in Brescia, which cultures field samples for the presence of microbiological contamination with *Salmonella* and generic *Escherichia coli (E. coli).*

As stated above, major concerns had been identified during the last audit of the Italian meat inspection system, which was conducted in January 1999. During this current audit, the auditor determined that none of the major deficiencies identified in the last two audits had been addressed or corrected.

Residue Program Audits: This audit was conducted by FSIS Residue Program Auditors. The audit began with a meeting by FSIS residue specialists and Italian Ministry of Health officials to discuss the National Residue Program, including the residue plan design, operations, compliance and enforcement. This was followed by on-site audits of pork slaughter establishments and swine farms located in three regions.

Laboratory Program Audits: This audit was conducted by FSIS chemists and a Quality Control Specialist from the Environmental Protection Agency and included visits to three laboratories--two performing analytical testing of field samples for the national residue testing program, and the third, the National Reference Laboratory.

This report is organized in three parts to reflect findings in each area of interest.

RESULTS AND DISCUSSION

SUMMARY

Inspection Program Audits

Government Oversight: The auditor reviewed records and other information to document the adequacy of the GOI's supervision of its national inspection program, including records pertaining to required monthly supervisory reviews of establishments certified to export to the US. In general, serious deficiencies were noted in establishments' HACCP plans, SSOP operations, sanitation controls, slaughter/processing controls, monthly supervisory visits, and use of microbiology methods for analyzing *Salmonella* samples, which demonstrate inadequate government oversight of the Italian inspection program. Specific audit findings are discussed later in this report.

Records Review: Eleven establishment's records were audited at Italy's inspection headquarter (14L, 37L, 335L, 350L, 478L, 550L, 586L, 596L, 908L, 1125L, 1157L). Records from establishments 14L and 37L were not provided by the GOI. The records review for the remaining nine establishments revealed several serious deficiencies in the areas of HACCP and SSOP. Specific audit findings are discussed later in this report.

On-Site Establishment Audits: Nine establishments (92 M/S, 272 M/S, 312 M/S, 478 M/S, 515 L, 643 M/S, 768M/S, 791 M/S, and 1329 M/S) were audited; two establishments (Ests. 312 M/S and 643 M/S) were judged acceptable subject to re-review on the next audit. Two establishments (Ests. 791 M/S and 1329 M/S) were found to be unacceptable and were delisted by the Government of Italy (GOI). The audit findings, including compliance with HACCP, SSOP, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Microbiology Laboratory: The auditor visited the government microbiology laboratory in Brescia, which cultures field samples for the presence of microbiological contamination with *Salmonella* and generic *Escherichia coli (E. coli).* The auditor found serious deficiencies in Italy's *Salmonella* testing program. Specific laboratory audit findings are discussed later in this report.

Residue Program Audits

Design of the Italian residue program is consistent with Council Directive 96/23/EC, supporting a focused, targeted approach for detecting the use of prohibited growth promotants. However, Italy's national plan does not include testing for some compounds that the EC requires of other Member States and Third Countries. In addition, no compounds are scheduled for Group B2e (NSAISs).

The release of the plan from the Central authorities is timely. However, the Regions differ significantly in implementing the sampling schedule at the local level (January 2000, March 2000, and April 2000).

There is an overall lack of awareness of new drug approvals within the EC and the relationship to US drug approvals. As an example, Flunixin is approved for use in cattle and swine in Europe. Since Flunixin is not approved for use in swine in the US, there should be no detectable levels of the drug in edible tissue exported to the US.

There are significant delays in reporting analytical results from the laboratories. Once results are reported, there are unclear lines of communication among Regions, despite the ability to move animals freely throughout the country. Adequate follow-through for reported violations was not evidenced.

Laboratory Program Audits

The National Reference Laboratory (NRL), Instituto Zooprofilattico Sperimentale Della Lombardia E Dell' Emilia-Romagna-Sede Di Brescia located in Brescia develops new methods for testing for residues. However, personnel from the two Instituti Zooprofeilattiei Sperimentali (IZS's) laboratories that were audited clearly stated they had rarely, if ever, received new methods from the NRL and had never implemented a NRL-developed method. Officials of the NRL stated that this function was begun in 1994 and that more effort had to be expended to implement the new NRL-developed methods. The two regional laboratories that were audited and the number of problems that were uncovered suggest that many more problems may exist in the unaudited laboratories.

Many analytes are not included in the residue control program (zeranol is analyzed, but taleranol is not; neither non-steroidal anti-inflammatory drugs (NSAIDs) nor flunixin are

included in the program). Many drugs are analyzed for feed rather than in the animal tissues (nitroimidazoles, chloramphenicol, tranquilizers (specifically, only promazine and benzodiazepine are included in the program, but only for animal feed; azaperone, proprioprom azine and carazolol are completely omitted from the program)). The sensitivity of several methods does not meet European Union (EU) or US sensitivity standards (DES, chloramphenicol).

The two IZS's used different methods to analyze for the same classes of compounds. The different methods encompassed different numbers of drugs and had different sensitivities. Two examples are sulfa drugs and avermectins. The net effect of this non-uniform approach is an unequal application of food safety standards.

The NRL is active in the Technical Scientific Secretariat, which has members from the Ministry of Health, Institute of Health and, apparently, the IZS's. Although the Secretariat is supposed to be involved in the harmonization of residue methods, this was not demonstrated in the review of the methods used by the two IZS's. Because of the lack of method harmonization, there are major systemic differences in analytical capability, capacity, and proficiency. While the Brescia and Turin IZS's did work cooperatively, there appeared to be a lack of leadership in bringing together all of the IZS's to share methodology, or to evaluate and compare laboratory performance.

The IZS's compete for funding to perform special projects. Brescia received such an award. Additional efforts may be needed to enable the IZS's to detect the levels and all of the analytes that the EU will require in the near future. The current number of staff and instrumentation appear to be inadequate to meet this challenge. Additional laboratory capability is needed (for example, LC/MS/MS methods) to meet both current and pending EU standards and US standards.

The NRL has recognized that its role needs to be expanded to include more resources assigned to method development and training, to conduct proficiency tests, to provide reference standards, and to conduct other activities to ensure consistency across Italy. Although this coordination had begun in the mid-1990's, there was no evidence of any tangible accomplishment in this area at the time of this audit. As a first step, the Institute is contemplating a reorganization in which the NRL would become a distinct organizational entity. Such reorganization could be beneficial because resources would be under the direct control of the NRL director. A more centralized program needs to be implemented.

There is a major problem related to confirmatory follow-up by the NRL for samples found to be positive by the IZS's. That is, the NRL stated that it performs confirmatory analyses for the IZS's upon request or when needed in support of regulatory or judicial action. The Turin laboratory found a positive clenbuterol sample in March 2000. [The actual sample had been taken at slaughter in mid-February.] Several months passed before the sample was sent, under judicial request to the NRL. As of mid-September 2000, the NRL had still not begun the analysis of this sample to confirm the presence of a prohibited substance. That activity does not appear to a high priority for the NRL.

Entrance Meeting

On September 11, an entrance meeting was held at the Ministry of Health in Rome. This meeting was coordinated by Dr. Piergiuseppe Facelli, Direttore Ufficio III, Ministero Della

Sanita, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria, and was attended by Dr. Alessandra Di Sandro, Dirigente Veterinario I Livello, Ufficio VIII; Dr. Silvio Borrello, Direttore Ufficio VIII; Dr. Franco Fucilli, Ufficio VIII Sezione Produzione Carni Fresche; Dr. Pietro Noe, Ufficio VIII Sezione Produzione Prodotti A Base Di Carne; Dr. Carla Campagnoli, Dirigente Veterinario I Livello, Ufficio XI; Ms. Annamaria Donato, Dirigente Farmacista I Livello, Ufficio XI; Dr. Agostino Macri, Dirigente del Laboratorio Veterinario, Istituto Superiore di Sanita; Dr. Patrizia Parodi, Dirigente Veterinario I Livello, Ufficio III; and Dr. Agostino Macri, Instituto Superiore di Sanita.

The US delegation was led by Mr. Donald Smart, Director, Review Staff, Food Safety and Inspection Service (FSIS), and Dr. Faizur Choudry, Lead Auditor, International Audit Staff. Attendees from FSIS were Ms. Rita Kishore, Chemist, Residue Program Auditor; Dr. Michael Hoffman, Chemist, Laboratory Auditor; Ms. Mary Stanley, Food Technologist, Residue Program Auditor; Mr. Gary Stefan, Animal Production Specialist, Residue Program Auditor; Dr. Manzoor Chaudry, Branch Chief Residue, Residue Program Auditor; Mr. Joel Salinsky, Quality Assurance Officer; Mr. Leon Ilnicki, Quality Assurance Officer; Dr. Elizabeth Leovey, Chemist, Laboratory Auditor, Environmental Protection Agency; and Mr. Clay Hamilton, Agricultural Attaché, American Embassy in Rome.

Topics of discussion included the following:

- Welcome by Dr. Piergiuseppe Facelli, Direttore Ufficio III, MH-Italy and an explanation of the Italian meat inspection system
- Overview of the National Residue Program database
- Discussion of the previous audit report and team audit concept

Subsequent to that meeting, the USDA team divided into three subgroups and pursued their individual audit goals.

INSPECTION PROGRAM AUDIT

Purpose: The purpose of this part of the audit was to evaluate Italian inspection system controls over establishments certified for export to the US.

Method and Scope: As stated earlier, the inspection program audit encompassed four separate activities: (1) government oversight, (2) records review of selected establishments, (3) on-site visits of selected establishments, and (4) a visit to the government microbiology laboratory.

Program effectiveness determinations were based on the four audit areas mentioned above and each audit area was evaluated according to FSIS' five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Italy's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program

delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect, and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the US, and are delisted accordingly by the country's meat inspection officials, which was the case with two establishments 791 M/S and 1329 M/S.

1. GOVERNMENT OVERSIGHT: There had been no changes in the organizational structure or upper levels of inspection staffing since the last US audit of Italy's inspection system in January 1999.

All inspection veterinarians and inspectors in establishments certified by Italy as eligible to export meat products to the US were full-time/part time either Ministry of Health or Regional/Local Government employees, receiving no remuneration from either industry or establishment personnel.

Serious deficiencies were noted in all aspects pertaining to government oversight of Italy's inspection system. These deficiencies were reflected in the lack of monthly supervisory visits to certified Italian establishments, and the recurring deficiencies noted in Italy's implementation of HACCP, SSOP, and *Salmonella* and *E. coli* testing in its certified establishments. In addition, sanitation controls and slaughter/processing controls were found to be generally inadequate to prevent actual or potential product contamination.

2. RECORDS REVIEW: The auditor conducted a review of inspection system documents pertaining to the eleven establishments selected for records review (14L, 37L, 335L, 350L, 478L, 550L, 586L, 596L, 908L, 1125L, 1157L). This records review was conducted at the Health Ministry Office in Rome. The records review focused primarily on food safety hazards and included the following:

- Supervisory visits to establishments that were certified to export to the US.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Pathogen reduction and other food safety initiatives such as SSOP, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Control of products from livestock with conditions such as tuberculosis and cysticercosis, and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the US.

The following concerns arose as a result of the examination of these documents. In the area of HACCP implementation and operation in the establishments, the auditor noted the following deficiencies.

1. In five out of 11 establishments, the HACCP plan did not adequately specify critical limit, for each CCP, and the frequency with which these procedures will be performed.

2. In seven out of 11 establishments, the HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit.

3. In one establishment out of 11, the HACCP plan was not validated to determine that it was functioning as intended.

4. In seven establishments out of 11, the HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOI meat inspection officials.

5. In one establishment out of 11, the HACCP plan's record keeping system was not documenting the monitoring of CCPs.

In the area of SSOP operations in the establishments, the auditor noted the following deficiencies.

1. In three establishments out of 11, the written SSOP program did not identify pre-operational sanitation.

2. In seven establishments out of 11, the daily pre-operational and operational sanitation SSOP monitoring records and any corrective action taken were not being maintained adequately. The Italian inspection officials were monitoring pre-operational sanitation of SSOP only four to five times a year and the records were not maintained adequately.

3. ON-SITE ESTABLISHMENT AUDITS: To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with US requirements. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

One hundred and twenty establishments were certified to export meat products to the US at the time this audit was conducted. Nine establishments were visited for on-site audits. In five of these establishments, both Italian inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. These five establishments were found acceptable. Two establishments were rated acceptable subject to re-review on the next audit because of several deficiencies regarding sanitation and the condition of facilities. Two establishments (Est. 791M/S, and 1329M/S) were rated unacceptable because of critical sanitation and contamination of product problems, which are discussed later in this report. Attachment F to this report presents the review findings for each of the establishments audited on-site.

The following operations were being conducted in the nine establishments:

Pork slaughter and boning – seven establishments (92M/S, 272M/S, 312M/S, 643M/S, 768M/S, 791M/S, and 1329M/S)
Pork boning and prosciutto ham in Establishment 515L
Pork boning and cooked ham in Establishment 478L

Sanitation Controls

As stated earlier, the auditor focuses on five areas of risk when assessing a foreign country's inspection system. The first of these risk areas that the auditor looks at is Sanitation Controls. These controls include the implementation and operation of SSOP programs in certified establishments, all aspects of facility and equipment sanitation, actual or potential instances of product cross-contamination, personal hygiene and practices, and product handling and storage.

Based on the on-site audits of establishments, Italy's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; separation of operations; temperature control; work space; ventilation; dry storage areas; ante-mortem facilities; welfare facilities; and outside premises. Lighting was inadequate in one establishment, but this deficiency was corrected.

The auditor's findings are presented below for the areas of SSOP, product cross-contamination, product handling and storage, and personal hygiene and practices.

Sanitation Standard Operating Procedures (SSOP): Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the US domestic inspection program. The data collection instrument used accompanies this report (Attachment A).
The SSOP were found to meet the basic FSIS regulatory requirements in the nine establishments audited, with the following variations.

1. In four out of nine establishments, the written SSOP procedure did not address operational sanitation.

2. In one establishment, the written SSOP did not specify the frequency for each procedure to be conducted.

3. In one establishment, the written SSOP did not identify the individuals responsible for implementing and maintaining the activities.

4. In six establishments, the records for SSOP operational sanitation and any corrective action taken were not being maintained.

5. In one establishment, the written SSOP procedure was not dated and signed by the person with overall on-site authority.

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in all nine of the establishments audited. In some establishments but not all, the GOI took corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F to this report. Examples of findings of actual product contamination include:

1. In three establishments, dripping condensate, from overhead refrigeration units, ceilings, pipes, ducts, and air vents that were not cleaned/sanitized daily, was falling onto carcasses and exposed edible product in the coolers, boning, offal and slaughter rooms.

2. In two establishments, water was leaking from an overhead pipe onto edible offal in the slaughter room and onto carcasses in the slaughter room.

3. In three establishments, sanitizers were not maintained at the required temperature (82ºC) in the slaughter and boning rooms during operation. In one of these establishments, the sanitizing facility for knives in the slaughter and boning rooms was designed in such a way that it was not possible to sanitize knives completely and effectively.

4. In one establishment, hog carcasses were contacting a sanitizer and water was splashing onto carcasses during sanitizing of the eviscerating saw in the slaughter and boning rooms.

5. In eight establishments, insanitary equipment was directly contacting edible product. For example, in one establishment, containers of edible product and racks for ham were found with fat, dried pieces of meat, and blood. In other establishments, edible product conveyor belts and working tables were found with grease, black discoloration, old meat scraps, and fat. A band saw and skin removal and neck bone separation equipment were found with dried meat, fat, and blood. Plastic bins, working tables, and numerous racks for hams and plastic containers of edible product ready for use in the boning and offal rooms were soiled with fat, pieces of dried meat, blood, and grease.
6. In one establishment, an automatic offal hook conveyor was soiled with blood, and fat and was not washed/sanitized as required during the operation. In one establishment, the automatic viscera conveyor was soiled with fecal material, ingesta, blood, and fat after washing/sanitizing in the slaughter room.

7. In one establishment, an employee was not washing/sanitizing a carcass splitting saw as required, due to fecal material/ingesta contamination or disease conditions. There was no convenient facility at the location to wash equipment where the employee was splitting carcasses.

8. In two establishments, pest control was inadequate. Numerous flies, mosquitoes, and other flying insects were observed in the slaughter and boning rooms.

9. In three establishments, overhead refrigeration units and ceilings in the coolers and boning rooms were observed with accumulations of fat, old meat scraps, and black stains. Overhead beams, pipes, supports, air vents, lights in the slaughter room, and areas around the two openings in the ceilings for conveyor chain for edible product in the boning room were observed with accumulations of dust, dirt, fat, pieces of meat, flaking paint, and black discoloration. Overhead exhaust fans and ceilings in the slaughter room were observed with accumulations of dust and cobwebs.

10. In one establishment, edible product was contacting a fork lift during transportation.

11. In one establishment, hog carcasses were contacting working platforms, a dirty ladder, and employees' boots at the evisceration, carcass inspection, and carcass branding stations in the slaughter and boning rooms.

The following is an example of a finding of potential cross-contamination of product:

- In one establishment, several doors between slaughter floor and employees' locker rooms and between boning rooms and shipping area opened upwards. Puddles of water below the doors resulted in dripping water that was observed to fall on employees' clothes and constituted a hazard for exposed product.

Product Handling and Storage: In the area of product handling and storage, the following deficiencies were found. The GOI took corrective actions in each instance.

1. In one establishment, gaps at the bottoms of doors in the slaughter, boning and shipping rooms, in the dry storage, equipment washing, and inedible product storage rooms were not sealed properly to prevent the entry of rodents and other vermin.

2. In one establishment, hog carcasses, which were retained for trimming for fecal material and ingesta in the slaughter room, were not handled in a sanitary manner. Carcasses were hung too close to each other with potential for cross-contamination.

3. In one establishment, edible-product was contacting walls and a dirty frame of racks in the cooler.

Personnel Hygiene and Practices: In the area of personnel hygiene and practices, the following deficiencies were found. In some establishments, but not all, the GOI took corrective actions.

1. In one establishment, one employee was observed using a dirty steel knife, which was kept in the sink and, without washing his hands or sanitizing his knife, handling edible product in the slaughter room.

2. Another employee was observed picking up a piece of meat from the floor and, without washing his hands, handling edible product in the boning room.

3. An employee was observed handling a dirty step ladder and, without washing his hands, handling hams in the processing room in one establishment.

4. In one establishment, a few employees in the processing room were observed wearing thread bracelets.

5. In one establishment, an employee was observed removing a dirty empty rack that had contacted an employees' platform and, without washing his hands, handling edible product in the boning room.

6. In one establishment, personnel in the boning room were observed with greasy, worn out and deteriorated aprons.

Animal Disease Controls

The second of the five risk areas that the auditor looks at is Animal Disease Controls. These controls include ensuring adequate animal identification, use of humane slaughter methods, control over condemned and restricted product, and procedures for sanitary handling of returned and rework product. Italy's inspection system had adequate controls in place to

ensure control over the above areas, with the following deficiencies. The auditor's findings are presented below for the area of animal disease.

1. Containers for edible and inedible product were not identified in two establishments. For one of the establishments, this is a repeat deficiency from the January 1999 audit. Establishment officials in both establishments ordered immediate correction.

2. In one establishment, one hog carcass, on an edible product conveyor belt in the boning room was observed with abscesses. The carcass was not properly identified and controlled to be trimmed effectively. Establishment officials took corrective action immediately and proposed modifications to improve carcass identification and prevention of cross contamination to the GOI.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous US audit. At the time of the audit, Italy had no positive cases for Bovine Spongiform Encephalopathy. At present, Italy is not free from hog cholera or swine vesicular disease.

Slaughter/Processing Controls

The third of the five risk areas that the auditor looks at is Slaughter/Processing Controls. These controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition, humane slaughter; post-mortem inspection procedures; post-mortem disposition; condemned product control; restricted product control; ingredients identification, control of restricted ingredients; formulations; processing schedules, equipment and records, and processing controls of cured, dried, and cooked products. The controls also include the implementation and operation of HACCP systems and generic *E. coli* testing programs. Deficiencies in this risk area are presented below.

HACCP Implementation: All establishments approved to export meat products to the US are required to have developed and implemented a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the US domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of the nine establishments. The auditor found the following deviations from FSIS regulatory requirements.

1. In seven of nine establishments, the HACCP plan did not specify critical limits for each CCP and the frequency with which these procedures will be performed.

2. In five establishments, the HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit.

3. In five establishments, the HACCP plan was not validated to determine that the plan is functioning as intended.

4. In eight establishments, the HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOI meat inspection officials.

5. In three establishments, the HACCP plan ‘s record-keeping system was not documenting the monitoring of CCPs.

6. In seven establishments, both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation associated with the production of the product, prior to shipping. The auditor explained the requirements for this pre-shipment review in detail and GOI meat inspection ordered immediate implementation.

7. In seven establishments, the zero-tolerances for visible fecal material/ingesta contamination, and milk on carcasses were not enforced by the GOI meat inspection officials and there was no monitoring record maintained to verify this activity. None of the above slaughter establishments included fecal material, ingesta contamination, and milk as food safety hazards and did not address these hazards as a critical control points in their HACCP plans.

Testing for Generic *E. coli*: Italy has adopted the FSIS regulatory requirements for generic *E. coli* testing. Seven of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the US domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The auditor noted the following variations.

- The generic *E. coli* samples are received and recorded in the laboratory on the same day and analyzed in four days. FSIS requires that the samples be analyzed no later than one day after collection.

- In one establishment, establishment employees were sponging carcasses and evaluating generic *E. coli* test results using excision samples criteria. If an establishment uses the sponge technique to collect a generic *E. coli* sample, then they must use statistical process control to ensure that their operations are under control, rather than the excision criteria. Establishment officials ordered immediate correction.

Enforcement Controls

The fourth of the five risk areas is Enforcement Controls. These controls include the GOI's enforcement of inspection requirements and its testing program for *Salmonella* species.

Inspection System Controls: Except as noted below, and with the exception of the unacceptable establishments (Est. 1329M/S and 791M/S), the GOI meat inspection system had controls in place for ante-and post-mortem inspection procedures and dispositions, restricted product and inspection samples, disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, and prevention of commingling of product intended for export to the US with domestic product.

Also, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans) were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled.

In addition, controls are in place for inspection supervision and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing, and these controls were effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species**:** Seven of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the US domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Italy has adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measure: The government laboratory uses ISO 6579 and AOAC 967.25 to analyze for *Salmonella.* The auditor found the following deficiencies.

- Instead of using FSIS-approved methods ISO 6579 and AOAC 967.25, the GOI was using ISO 7251 and AOAC 991.14 to analyze samples for *Salmonella*. Both of these methods are used to test for generic *E. coli* not *Salmonella*. The GOI stated in the documents submitted to FSIS in 1999 and 2000 that they would like to use ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella* instead of the FSIS methods. FSIS found the methods--ISO 6579 and AOAC 967.25--to be equivalent to the methods FSIS uses, and conveyed this equivalence determination to Italy. Before new methods can be used, Italy must submit a request to FSIS for an equivalence determination. No such request has been made by the GOI to date.

- The *Salmonella* samples are received and recorded in the laboratory on the same day and are not analyzed until four days after collection. FSIS requires that the samples be analyzed no later than one day after collection.

- Fifty-five *Salmonella* samples were taken from each hog slaughter establishment in 1999. This size sample set meets the FSIS requirement under the Pathogen Reduction/HACCP rule for a sample set for swine. However, during calendar year 2001, the GOI meat inspection officials decided to only take a set of 25 samples from each hog slaughter establishment instead of the required 55 samples. GOI meat inspection officials took corrective action immediately.

Species Verification Testing: At the time of this audit, Italy was not exempt from the species verification testing requirement. However, the establishments visited on-site were not producing processed products, and therefore species verification testing was not required.

Listeria monocytogenes: Establishments producing ready-to-eat products have a surveillance program for *Listeria monocytogenes.* The establishments test between two to four samples per week for *Listeria monocytogenes*. However, the establishments did not reassess their HACCP plans to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

Monthly Reviews**:** FSIS requires that monthly supervisory visits be performed in certified Italian establishments. However, the GOI was not performing monthly supervisory visits in establishments certified to export to the US. Local or regional officials were only conducting one or two reviews per year. These reviews were being performed by the Regional/Local Officials equivalent of circuit Supervisors, and they were all veterinarians.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, in most establishments only two or three reviews per year. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the regional/local offices.

If an establishment is found during one of these internal reviews to be out of compliance with US requirements, and is delisted for US export, before it may again be eligible to be reinstated, regional/local officials must conduct an in-depth review, and the results are

reported to the GOI in Rome for evaluation. GOI officials then formulate a plan for corrective actions and preventive measures.

Enforcement Activities: Enforcement activities are carried out by regional/local government officials, who have full power to initiate all enforcement actions. Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, and adequate controls for security items, shipment security, and products entering the establishments from outside sources.

Additionally, establishments had adequate controls in place to prevent meat products intended for Italian domestic consumption from being commingled with products eligible for export to the US.

4. Microbiology Laboratory Audit

Italy's microbiological testing program for *Salmonella* and generic *E. coli* was being performed in the government laboratory at the Instituto Zooprofilattico Sperimentale Della Lombardia E Dell' Emilia-Romagna-Sede Di Brescia in Brescia. Results of the audit of the microbiological laboratory are presented earlier in this report: *Salmonella* testing can be found under Enforcement Controls; and generic *E. coli* testing can be found under Slaughter/Processing Controls.

The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping capabilities. The intra-laboratory check sample program was carried out as follows: three samples are given twice a year to each analyst. Results of analyses were being reported to the inspection authorities of the government and the establishment.

RESIDUE PROGRAM AUDITS

Purpose of Mission: To evaluate the effectiveness of the Italian residue control program for red meat and poultry products. Emphasis was placed on the residue controls associated with pork production, given that this is the only commodity exported to the US at this time.

Method and Scope: The residue program review subgroup met with Italian officials from the Ministry of Health (Ministerio della Sanita) (MINSAN), Department of Foodstuffs, Nutrition, and Veterinary Public Health (Dipartimento degli Alimenti, della Nutrizione e della Sanita Pubblica Veterinaria) (DANSPV) at the onset of the mission. This purpose of this meeting was to obtain background information from the appropriate competent authority regarding organization, roles and responsibilities and an overview of the residue control program. During the remainder of the week, the residue review subgroup conducted on-site visits to pork slaughter establishments and swine farms located in three regions (Lombardia, Piemonte, and Lazio). A meeting was held at the end of the week, providing preliminary findings of the audit. During all visits, a representative from the appropriate office accompanied the residue review subgroup.

Objectives of the Residue Program: The primary objective of the Italian residue control program is to provide an effective and uniform monitoring system to detect the presence of chemical residues in live animals, feed components and meat products. A targeted sampling approach is used with regard to the use of illegal substances in animals, while surveillance

sampling is aimed at verifying compliance with the maximum residue limits (MRL) of approved veterinary medicinal products and other contaminants in foodstuffs of animal origin. The appropriate authorities collect specified tissues, which are analyzed at designated laboratories. Tissue samples, such as the muscle around the injection site, are also collected from suspect animals or carcasses at the discretion of the inspector. The causes of residues in food of animal origin are investigated, as well as sampling increased to assure detection of additional non-compliant products and to deter future misuse.

Organization and Legal Authority

Organization: The MINSAN, through various offices within the DANSPV, is responsible for the design and implementation of the residue control program. This includes the annual update of the National Residue Plan (PNR), coordinating the activities of the central and regional authorities, summarizing the results reported semi-annually by the regions and submission of these findings to the European Commission. The PNR establishes the number of samples to be collected for each compound, each species to be sampled and at what location (farm or slaughter establishment).

There are 21 regions in Italy, each with responsibility to implement the PNR at the local level. The Regional Veterinary Services are autonomous with regard to statutory, legislative, administrative and financial matters. While the authorities at the regional level are in charge for planning, organizing and coordinating inspection activities, including residue controls, the local services perform the actual duties. DANSPV Office VIII coordinates regional monthly inspection visits, though there is no evidence that these visits include any oversight of the residue program.

Each region coordinates the implementation of the local plan with the Aziende Sanitarie Locali (ASL) local veterinary services, of which there are 228 distributed throughout Italy. This local veterinary service has three functional areas: Area A—animal health issues (on the farm); Area B—public health or meat hygiene issues (sample collection at the slaughterhouse); and Area C—animal husbandry and farming production issues (sample collection on the farm and at feed mills). Each area works closely to ensure the program is followed.

DANSPV has specific responsibilities for developing Italian legislation and program instructions on the residue program, including sampling at the slaughter establishments and for analyses at the designated laboratories. Oversight at the laboratories, including accreditation, analyses techniques, sample treatment procedures and distribution of the results is the responsibility of the National Institute of Public Health (Instituto Superiore di Sanita—ISS).

Legal Authority: The National legislation of the MINSAN is based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC) and the control of residues on live animals and animal products (Council Directive 96/23/EC). These directives have been transposed into Italian law through the Legislative Decree No. 336 of August 4, 1999.

Regarding approval and use of animal health products, EU Regulation 2377/90/EC lists the drugs permitted for therapeutic use in each species of food animals, establishing MRLs per species per matrix. This regulation also lists products not requiring an MRL, products for

which a temporary MRL has been established and a list of products banned for the use in livestock.

Residue Plan Design, Review and Approval: Since 1988, Italy has implemented a specific statistically-based residue control plan for the detection of residues in pork intended for export to the US. For each compound, 300 samples are collected with sampling distributed equally among the slaughter establishments eligible to export to the US. At the time this approach was negotiated, Italy did not have a national residue control program in place. However, this US plan is now in addition to the PNR, which complies with the provisions of European Council Directive 96/23/EC. At the request of MINSAN, the need for continuing an additional residue plan specific to the US has been evaluated by FSIS, International Policy Staff.

Since 1998, MINSAN has coordinated a working group of technical experts, comprised of representatives from the Regions, ASLs, Regional laboratories (Instituti Zooprofilaltic Sperimentali or IZS), the National Reference Laboratory (ISS), and the Nucleo Operativo Regionale di Vigilanza (NORV). These experts identify specific compounds that are to be included in each group of substances outlined in Council Directive 96/23/EEC. Scientific literature, guidance from the Commission, available laboratory methods, as well as violative results from the previous six months are used to identify compounds. The draft PNR is reviewed and accepted by committee prior to the final plan being distributed to the Regions by mid-December. The Regions are expected to immediately implement the plan. In addition, the PNR is submitted to the EC for subsequent review and approval. Results of the EC review for PNR 2000 had not been received at the time of the audit.

Since 1998, the PNR has been modified only slightly, including the addition of two (2) compounds from Group A (Substances with Anabolic Effects or Non-authorized) to the residue plan, the distinction of the ∃-agonists being analyzed and changing Ivermectin to Avermectin. It should be noted that the plan does not include nitroimidazoles and carazolol in swine, which are required by the Commission of other EU Member States and of Third Countries. Further, there are no non-steroidal anti-inflammatory drugs in any species being analyzed (Table 1).

Table 1: Modifications and Deficiencies to ITALY's PNR

GROUP	COMPOUNDS	1998	1999	2000
A3 Steroids	16 OH Stanozolol	-	-	X
	Synthetic steroids	-	-	X
A5 ∃-agonists	Clenbuterol Salbutamol Isoxsuprine	-	-	X
A6 Prohibited Substances	Nitroimidazoles	X (turkeys only)	X (turkeys only)	X (turkeys only)
B2a An thelmintics	Ivermectin Avermectin	- -	X -	- X
B2d Sedatives	Carazolol	-	-	-
B2e NSAIDs	NONE	-	-	-

The process for identifying compounds for the PNR does not consider newly approved drugs at the Community level. The lack of testing for NSAIDs is a potential problem, since flunixin is a recently approved drug for use in swine in Europe (MRL = 50 :g/kg in muscle). However, flunixin is not approved for use in swine in the US, which impacts the accepted tolerance for detectable residues. Since this drug is not included in the Italian residue plan, there cannot be assurances that there are no detectable residues present in pork.

Consistent with EU legislation, Italy uses a targeted approach to all residue sampling, applying the specified levels and frequencies from Directive 96/23/EEC. Sample frequencies are based solely on animal production levels. Regional authorities may not reduce the predetermined level of sampling designated for their Region, though they do have the option to increase the total number of samples if needed. This increase in sampling is reported separately from the monitoring samples collected under the PNR, either as "suspect" sampling or "other" sampling. It was noted that the Italians are exploring a statistical basis for determining sampling frequency for CY 2001.

In addition, the Italian authorities indicated that results from previous years are considered and adjustments are made to the monitoring sample frequency. However, there are no set criteria for increasing the sampling number based on violations. Further, the increase in targeted sampling is not evidenced during implementation. As an example, there were 16 reported violations for B1 compounds in bovine in 1999, yet the sampling rate for the monitoring plan from 1999 to 2000 remained constant (veal calves=600, young bovine=450 and cows=450).

Residue Plan Operations

Lombardia Region: There are six districts in the Lombardia Region, which are serviced by fifteen ASL (Provencia). The slaughter establishment visited, which is one of approximately 60 slaughter establishments in the Region, as well as the farm are located in Distretto di Viadana.

Upon receiving the PNR from MINSAN on December 20, 1999, the Lombardia Region distributed the targeted sampling plan for each ASL, based on production volumes (number of animals slaughtered for each species), on February 28, 2000. The District generated the specific sampling plan for each individual slaughter establishment. Though the annual sampling plan was not received at the slaughter establishment until March 2000, the inspection official continued to collect samples based on the previous year's plan.

In Slaughter Establishment: There are four types of residue samples collected at the slaughter establishment by the GOI veterinarian: PNR monitoring samples, U.S plan monitoring samples, intensified sampling as a result of follow up action from a previous violation and suspect samples. The PNR sample schedule is provided on an annual basis. Sample collection schedules for the US plan are provided to the GOI veterinarian at the slaughter establishment every month. Sample collection is evenly distributed throughout the year.

The GOI veterinarian verifies the information that accompanies each shipment of live hogs, including all man-made animal identification numbers present on the animal (tattoos or ear tag numbers), name of the owner, producer, and the transport company. Any producer with a history of previous violations will have 10% of the animals sampled at the slaughter establishment as follow up action.

The GOI veterinarian has the option to select an increased number of samples, due to a higher level of suspect animals being presented. These samples are not included as part of the PNR. Two samples were collected in May 2000 for CHC at the establishment that was visited, which were identified as "suspect" on the sample request form submitted to the laboratory. Product was not retained pending the results of these tests. The results of these analyses were not available at the time of the audit.

When samples are collected, two sets of the appropriate tissue samples are identified with pre-printed labels according to established procedures. Samples are stored in double plastic bags and an official seal is applied. The samples are stored in the freezer located in the inspector's office until transported to the designated laboratory.

Under routine procedures, the laboratory reports results to each ASL, who reports the results to the GOI veterinarian at the slaughter establishment, as well as the Region. The Region routinely reports summary data to MINSAN 2 times each year based on results provided by each ASL. However, when the laboratory detects a violative level, notification is immediately faxed from the laboratory to the MINSAN as well as the Region and ASL that submitted the sample. Written notification is provided to the Region where the animal originated. No other Region is made aware of the positive results.

There was a violation reported for sulfamethazine in this establishment in June 2000. Notification was provided to the MINSAN, as well as the Region where the animals originated. However, there was no documentation an investigation was initiated or that any additional sampling was taken as a result of this violation. Further, there was no oversight or follow-up action taken by MINSAN related to this violation.

On Farm: A full time private veterinarian makes the diagnosis, prescription and administers the drugs for treatment. Animals are identified by a single earmark, which identifies the farm, as well as a stamp on the ham that indicates Parma, the month of the birth of the animal and the code for the farm (premises). Feeds are mixed on location, however there are no documented procedures for mixing the medicated feeds. Sequencing is used when transitioning from medicated to non-medicated feeds, with the first batch of non-medicated feed being diverted to young pigs or breeding stock that will not be going to slaughter in the next 90 days. The farm is required to analyze one sample of medicated feed each year to demonstrate the feed mixing equipment and procedures used are appropriate/adequate.

The swine farm that was visited is licensed to store animal drugs on site. Farms must be specifically approved to store animal drugs on the premises. On those farms which are not approved to store drugs, the veterinarian may only prescribe drugs in amounts that can be used immediately. Records are maintained on all animal drugs requiring prescription, which are written in triplicate so that copies can be maintained by the prescribing veterinarian, filed at the farm, provided to the District where the farm is located and provided to the pharmacy/wholesaler dispensing the drug. The ASL veterinarian cross-checks and verifies all the prescriptions written or dispensed in the District.

Certificates (affidavits) are issued for every group of animals moving off of the farm, whether to another farm or to slaughter. Any drugs applied to animals within 90 days of slaughter will be recorded on the transportation documents, with a copy of the prescription attached. Drug inventory and use records are maintained and all drugs are controlled in a

locked cabinet or refrigerator. However, no written operating procedures are maintained by the operation.

On-site visits by the ASL veterinarian (Area C) are scheduled annually to review the record keeping for veterinarian drug use and checks on feedstuffs. The PNR 2000 for this District schedules on-farm samples of feed for chloramphenicol and nitrofurans, which are collected by this individual. No samples are scheduled or collected from live animals under this plan.

Reporting Positive Results: Although no violations had occurred at the farm visited, the Regional authorities confirmed that violations are followed up on a case-by-case approach, depending upon the substance in question. At the farm, the ASL will increase inspections but may not take a sample every time. Intensified sampling is statistically based, and if over half of the samples are positive, the entire herd will be destroyed. If the substance is prohibited, there are criminal sanctions resulting in arrest and possible fines/jail.

Piemonte Region: The 22 local veterinary services (ASL) throughout the Region are responsible for inspection activities in the meat and poultry establishments as well as the farms. The slaughter establishment and farm visited were in ASL No. 8—Chieri.

The Piemonte Regional Coordinator received the PNR from MINSAN on December 20, 1999 and generated the targeted sampling plan for each ASL, based on the animal production levels reported from the previous year. This plan was distributed to the ASLs, as well as MINSAN, ISS and IZS on April 19, 2000. Each ASL generates monthly sampling plans specific to the farms and slaughter establishments in their local area, to ensure random yet continuous sampling. The high number of animals slaughtered, combined with multiple analyses for each sample, accounts for the large number of samples reported.

The US plan was generated by the Regional Coordinator and received by the ASL on February 10, 2000. Sample collection schedules for the US plan are equally distributed between all the slaughter establishments eligible to export to the US in the ASL. These schedules are generated monthly and provided to the GOI veterinarian.

Each ASL must report results to the Region every six months, which in turn is summarized and reported to MINSAN. All ASL data are cross-checked with the reports from the laboratories, which are sent directly from the laboratory to the Region, as well as the ASL.

In Slaughter Establishment: The GOI veterinarian develops the sampling plan specific to the slaughter establishment for both the US plan, as well as the PNR, based on the sample numbers designated. In addition, the local veterinarian has the discretion to select samples from suspect animals beyond the scheduled samples, though none was evidenced.

Following procedures similar to those used in the Lombardia Region, the GOI veterinarian verifies the information that accompanies each shipment of live hogs, including all man-made animal identification numbers present on the animal (tattoos or ear tag numbers), name of the owner, producer, and the transport company. Any producer with a history of previous violations will have 10% of the animals sampled at the slaughter establishment as follow up action. However, no violations have been reported in this slaughter establishment in the past three years so no follow up samples have been taken.

When samples are collected, four sets of the appropriate tissue samples are identified with pre-printed labels according to established procedures. Samples are stored in double plastic bags and an official seal is applied. It was noted that different seals are used in different Regions. The samples are stored in the freezer located in the inspector's office until transported to the designated laboratory.

The laboratory reports violations directly to the Region and MINSAN via e-mail. The Region coordinates additional samples that are to be collected at the slaughter establishment when animals are presented from producers with previous violations. Carcasses are detained pending results in this case. Since no violations had been reported at the establishment visited, there were no cases to follow up on. However, there were 2 violations reported by the Region in the first 6 months of CY2000 for corticosteroids. Details related to follow up investigations, for these violations or any other violations investigated by the Region were requested. However, the information was not provided.

On Farm: The farm that was visited primarily raises poultry, though two buildings are dedicated to swine production. The farm is not licensed to store drugs on location. The full time private veterinarian makes the diagnosis, prescription and supplies the amount of drugs sufficient to treat the size and number of animals. Initially, the private veterinarian indicated small quantities of unused portions of the drugs were left with the producer for the next treatment. This response was corrected after discussion with the Regional veterinarian. The producer maintains drug treatment records, as well as records on incoming animals and those leaving for slaughter. Animals receiving treatment are identified as a group, with individual collars being placed on those receiving the treatment. An affidavit is generated when transported to slaughter, which will document the drug treatment and withdrawal period.

All medicated feeds used on this farm are purchased pre-mixed, rather than mixing on location. Separate silos are used for medicated and non-medicated feeds and are properly labeled. However, there are no written procedures for cleaning out silos between medicated feeds. Initially, the private veterinarian indicated that only the silo is cleaned following the use of a medicated feed. However, when prompted by the Regional veterinarian, he indicated the entire feed delivery system is cleaned.

Lazio Region: The slaughter establishment and farm that were visited in this region were located in ASL No. RMH (Distretto Di Pomezia).

The PNR was received by the Region on December 20, 1999, and sample distribution was divided based on animal production within the ASL. This regional plan was distributed to the local ASL on January 27, 2000. The ASL defined the number of samples to be collected among the establishments under their authority and the annual sampling plan was distributed to each establishment. The GOI veterinarian at the establishment is responsible for sample distribution throughout the year.

In Slaughter Establishment: The limited time spent in this establishment was focused on sample collection according to the US plan. The ASL distributes the targeted number of samples equally among the establishments approved for export to the US. This schedule is provided to each establishment at the beginning of the year (January 31, 2000) and the GOI veterinarian at the establishment randomly selects samples throughout the year. The sampling frequency in the establishment visited was about 3 samples per month. The farms supplying the live animals to the slaughter establishment are located in Northern Italy. All

incoming documents are reviewed and US destined product is maintained separate from domestic production.

The laboratory reports results of analyses directly to the ASL. No violations have been reported on official samples at the establishment visited, but regulatory action was taken as a result of a violation for sulfamethazine reported from a sample collected by plant management at the processing establishment. Once the hams complete the curing process, the local ASL will collect additional samples before the product will be released into distribution. In addition, the producer has been subjected to increased sampling.

Enforcement Action: The laboratory reports results to the MINSAN, the Region, and the local ASL responsible for the slaughter establishment where the GOI veterinarian collected the samples. When a violation occurs, there is mandatory notification to the local ASL where the animals originated. This local health unit has the responsibility to investigate, and if appropriate, increase sampling on the farm. The Region will administer any criminal or civil infringement action, as outlined in Italian law 336/99. However, there was no evidence of follow through between Regions if the animal originated in a different Region than the one in which it was slaughtered. There is also a lack of National system for coordinating enforcement activities among the Regions, which weakens the effectiveness of the program.

According to procedure, additional sampling should be collected at the slaughter establishment when animals from the producer are presented for slaughter, though there is no reference to the number of additional samples that are to be collected. Since there were no reported violations for animals produced and slaughtered in the Regions visited, the level of increased sampling could not be verified. Further, since notification of violations is limited to the Regions involved with the production and slaughter of the animals, it would be possible for a producer to present animals for slaughter in a third Region, thereby avoiding any additional sampling.

Findings

Organization and Legal Authority

There is no direct line of oversight or management between the Central authorities (MINSAN) and the local authorities (ASLs). While no specific problems were identified, there were major variations between Regions in their application of the PNR. The lack of harmonization complicates the process and leaves the program vulnerable to different interpretations.

Residue Plan Design

1. Design of the residue program is consistent with Council Directive 96/23/EC, supporting a focused, targeted approach for detecting the use of prohibited growth promotants.

2. The release of the plan from the Central authorities is timely. However, the Regions differ significantly in implementing the sampling schedule at the local level (January 2000, March 2000, and April 2000).

The GOI responded that Italy does not have a centralized system, but that the Regional authorities have the responsibility for the implementation of these programs. Italy is

developing a system that will link the laboratories, Regions and local ASLs, which will help with the implementation and data management. It should be noted that the Italian officials did not see a concern about the differences between Regions.

3. There is an overall lack of awareness of new drug approvals with in the European Community and the relationship to US drug approvals. As an example: Flunixin is approved for use in cattle and swine in Europe. Since flunixin is not approved for use in swine in the US there should be no detectable levels of the drug in edible tissue exported to the US. FSIS expects that the GOI will establish a process to monitor and control drugs that not approved in the US, but that are approved in Europe and used in Italy.

The GOI indicated that their Residue Program is approved by the EC, and Italy is in compliance with EC Directive 96/23/EC.

4. Italy's national plan does not include testing for nitroimidazoles or carazolol in swine, even though the EC requires other Member States and Third Countries to include these compounds in their sample plans. In addition, no compounds are scheduled for Group B2e (NSAIDs).

5. Systematic analyses of results from previous year do not result in an increased level of sampling for compounds with repetitive violations reported.

Residue Plan Operations

1. Procedures are in place to collect and analyze samples collected both at the farm and in the slaughter establishment, according to the plan design. Though variations were observed among Regions, sample security and documentation was effective.

2. There are many positive aspects noted on the farms, including the registration of the farm, animal identification requirements, controls on animal drugs through the drug use record keeping requirements, the on-farm inspections by the ASL, and the certification system for the movement of animals.

3. There is no process in place to provide internal controls to verify the accuracy of information presented on the certification documentation submitted by the farms for the live animals. Incorporating such an audit function into the program could further strengthen the certification program.

4. Requirements for mixing and using medicated feeds on the farm are weak. There are no written procedures for mixing feeds, sequencing from medicated to non-medicated feed, cleaning equipment, etc. The requirement to only analyze one sample of medicated feed per year, regardless of the number of different medicated feeds manufactured, may not be adequate given that different drugs/feeds have different mixing characteristics.

5. Level of producer/veterinarian understanding of the PNR is of concern. Inconsistent responses to questions during interviews and strong prompting by regulatory officials from MINSAN raised concerns about the knowledge base and overall understanding of the program requirements.

The GOI agreed to address this concern immediately.

6. The significant delays in reporting results from the laboratory on samples collected, both for monitoring and enforcement plans, compromise the effectiveness of the PNR. FSIS expects that the GOI will address this significant deficiency immediately.

An Italian inspection official attributed this problem to technical problems in the laboratories. No solutions to the problem were offered.

Enforcement

The lack of a centralized, automated data processing system negatively affects the ability to rapidly communicate information to all segments of the animal health protection system. The lines of communication among Regions are not clear, in spite of the ability for animals to move between regions. Adequate follow-through for reported violations was not evidenced.

The GOI stated that it is working to develop a National system.

LABORATORY PROGRAM AUDITS

Purpose of Mission: To evaluate the effectiveness of the analytical laboratory support of the Italian residue control program for red meat and poultry products. Emphasis was placed on the laboratory capability and coordination within the system of laboratories.

Method and Scope: The laboratory program review subgroup met with Italian officials from the Ministry of Health (Ministerio della Sanita) (MINSAN), Department of Foodstuffs, Nutrition, and Veterinary Public Health (Dipartimento degli Alimenti, della Nutrizione e della Sanita Pubblica Veterinaria) (DANSPV) at the onset of the mission. This purpose of this meeting was to obtain background information regarding organization, roles and responsibilities of MINSAN and DANSPV and an overview of the entire residue control program. During the remainder of the week, the laboratory review subgroup reviewed the operations of three laboratories. Preliminary audit findings were presented to MINSAN and DANSPV at an exit conference held at the end of the week.

Findings and Recommendations

National Reference Laboratory

The evaluation team visited the NRL for approximately three hours and split into two sub-teams. One team discussed the PCBs, Dioxins and the QA system, while the other discussed detection limits and visited the laboratories.

The NRL located in the Ministry of Health's National Institute of Health, is a matrix organization in which the resources from four laboratories are assigned to this function, rather than as a distinct organizational entity in the Institute. Each laboratory is responsible for specified methods. The Veterinary Medicine Laboratory is responsible for Beta-agonists, steroids, stilbenes and other prohibited compounds. The Food Laboratory performs antibacterial tests (four plate tests); the Applied Toxicology Laboratory tests for organochlorines; and the Laboratory of Comparative Toxicology and Ecotoxicology conducts PCB and Dioxin methods. No group within the NRL was listed as being

responsible for the sedatives (B2d). [This deficiency was discussed at the exit conference and was resolved.] The NRL's director also heads the Veterinary Medicine Laboratory.

The total number of personnel assigned to the NRL is 15 senior staff, 10 technicians or assistants, and 15 contractors. The contractor divisions are divided as follows: Veterinary Medicine, 3, 4 and 4; Food Laboratory, 6, 5, and 9; Applied Toxicology, 4, 1 and 1; and the Laboratory of Comparative Toxicology and Ecotoxicology, 2 researchers and 1 contract personnel. The senior staff and some of the technicians and contractors have the equivalent of doctoral degrees from the Italian educational system.

During this evaluation, the individual in charge of quality assurance for the Institute was on vacation. According to laboratory personnel, the Institute has a Quality Assurance program that covers all of the laboratories. Each laboratory has an individual whose responsibility is QA and who reports to the laboratory director. The NRL participated in a couple of proficiency tests per year. The NRL was designed to be a source of reference standards, methods, and confirmation of analysis submitted to them by the IZS's. [The two IZS's reviewed reported that the NRL has provided little support in the past, though both commented that the methods provided by the NRL had not been implemented because they did not improve upon current methods, or funds for required instrumentation were not available.]

Instituti Zooproficlattici Sperimentali - Brescia

The Brescia IZS chemistry laboratory was reviewed over a period of one and one-half days. The chemistry laboratory is one of a number of laboratories that comprise the Institute. Most of the staff had chemistry or veterinary medicine degrees; several of the staff had advanced training. The Bologna satellite laboratory has a chemist and technicians, while the Milan laboratory has only technicians.

The Institute received its accreditation from SINAL in 1997. The Institute's QA director accompanied the team and was very helpful throughout the evaluation. Whenever a problem was noted, the QA director discussed it with the staff and recommend follow-up actions. The Institute has a QA manual that covers all laboratories in the institute and all local laboratories. Each laboratory within the Institute has a quality coordinator.

The quality coordinator for the chemistry laboratory also oversees the section analyzing anabolics. This represents a potential conflict of interest. Procedures and methods are described in Standard Operating Procedures approved by the Institute's QA director.

The QA director conducts audits of each laboratory, including the satellite laboratories in Bologna and Milan, accompanied by a technical expert. The QA director evaluates implementation of the Quality Manual while the technical expert evaluates the implementation of Standard Operating Procedures (SOP's). The technical expert is generally a quality coordinator from another laboratory. The Chemistry Department's quality coordinator accompanies the QA director on his audits of the local laboratories. SOP's exist for these audits and for implementing corrective action. Implementation of corrective action is reviewed in subsequent audits. Audits are conducted yearly. Proficiency testing is conducted of the local laboratories.

Standard Operating Procedures are also available for staff training and certification. Section leaders determine acceptable performance.

The laboratory has numerous forms to track samples and document results. Samples upon receipt are logged into a database from which final reports are generated. Five aliquots per sample are collected for the following use: analysis, back-up analysis, confirmation, the producer, and legal system samples. Unused samples are frozen for storage.

Deficiencies noted in documentation were minor, such as incomplete documentation of the preparation of reagents and standard solutions and incomplete documentation of columns used. It would have been impossible to trace the standard used for a specific analysis. The condition of a sample upon receipt was difficult to trace. Reference standards are not checked against previous standards to ensure proper preparation. The QA Manager indicated these problems would be immediately addressed.

Most of the documentation for samples is stored in offices for one year and are then moved to the archives. Due to the lack of space and time to operate an archive, files are stored in cardboard boxes. The inspectors' forms were stored in a cabinet, and those for the last year were on a table and were in consecutive order. An infrequent use of whiteout was observed on some records.

The laboratory is following current EU practices for determining Limit of Detection and Limit of Quantitation, and staff has reservations about the EU proposed method validation scheme because of the time involved.

The laboratory has classified methods into two categories; those validated following the current SOP, and historical methods for which the laboratory has an "understanding of the performance of the method." The thyreostat method is one such historical method. Validation data were not available for this method. Nor was this method written into the current formal format. The reviewers were told the methods are either accredited (SINAL) or Non-Accredited (all others). Thyreostat is a "non-accredited" procedure, written about 10 to 12 years ago and has been updated throughout the years. However, no data was available at the laboratory to support revisions or validation of the method.

While observing the thyreostat method, reviewers noticed that the analyst did not microfilter an unclear sample extract prior to injection. The written method leaves the decision to filter the extract up to the analyst. However, the supervisor agreed that that particular sample should have been filtered prior to injection. The laboratory's SOP specifies that the limit of detection is obtained from the mean of the baseline noise +/- nSD while the limit of quantitation is tLOD where t is generally 3.3. Results are not corrected for recovery.

The laboratory develops most of its own methods. A method is acceptable if the recovery is above 50% and precision is less than 15%. A lower recovery may be acceptable if the precision of the method is smaller. Incurred samples are not used in validating methods because of their limited availability. No internal check samples for the analysts were apparent. It did not appear that all analysts were involved with proficiency tests.

The chlorinated hydrocarbon (CHC) method was examined. It was found that some of the reported recoveries were less than fifty percent or greater than 150 percent. No corrective action process was in place for dealing with such results. Evaporation of CHC sample

extracts was done on four rotary evaporation units. There was no record of which unit was used with which samples.

The file for a positive clenbuterol analysis by LC/MS was reviewed. The results could be verified. In this analysis, an ELISA screen using three kits was performed. Positive results are rescreened by TLC and then HPLC/UV. The identity was confirmed by LC/MS.

Laboratory personnel reported they obtain their reference standards from industry and not from the ISS. It appeared that check sample programs usually involve participation in Ring/proficiency tests, frequently conducted by Techna and FAPAS. The proficiency samples are received once per year per analysis. Even when more than one analyst performs a given analysis, only one would participate in proficiency testing and receive an unknown proficiency sample. Reviewers noted that values for internal check samples are unknown to the analyst and were not used to provide a more frequent verification of either the method or the performance of the analyst.

Instituti Zooproficlattici Sperimentali - Turin (Torino)

The review team spent approximately half a day at the Turin Institute. The Institute has three laboratories with a staff of four degreed chemists and 15-16 technicians. The educational level of the technicians appears significantly lower than found in the Brescia laboratory and is a concern.

The laboratory was accredited by SINAL in 1998 for 80 methods. Two members of the team met with the QA staff. The Institute has a QA director. As in Brescia, the laboratory has a QA manual that describes the overall organization and implementation of QA. Specific methods and procedures are described in Standard Operating Procedures. SOP's for methods, including validation, are kept in the laboratory. Systems and technical audits are performed following ISO 30001. A lead chemist auditing another group conducts technical audits.

The laboratory prepares its own reference standards and blind samples. Ring tests were purchased form Techneca and FAPAS. The QA staff does arrange or oversee ring tests.

New employees receive training on the QA systems and SOP's. The supervisor develops a training plan that follows a SOP. Chemists certify the performance of technicians. Training records are kept for ten years.

Sample documentation was thorough in this laboratory. Samples were logged into a database that was accessible to everyone in the laboratory via a LAN system. As samples were analyzed, technicians would enter information into a database. Hard copy forms verified that procedures were performed. The technician and supervising chemist verified entries and co-signed the documentation. A cursory review of their documentation showed documentation of procedures, reagents, solvents, samples, methods, etc. Records are maintained for a year within the laboratory and then placed into the archives. Records are kept for ten years.

The Turin laboratory has official and internal methods. Most chemical methods are internal and are validated within the laboratory. Check samples, internal and unknown, were used in the methods observed.

It was observed that the use of quality control charts depended upon the analysis and whether the chemist used them. Control charts were used for most analyses, but not all.

Analysts are trained and then given a final test (sample), which is unknown to the analyst. The QA person monitors testing, and the lead chemist approves the results. One of the four chemists does the technical audit. The training is designed for each person, depending upon his or her background. Training is not standardized. All personnel have training documents.

This regional laboratory cooperates with the Brescia laboratory and has shared some methodologies. According to the staff at the Turin Institute, the Brescia Institute is a leading IZS.

Exit Meetings

Two exit meetings were conducted in Rome: one on September 15 and the other on September 29, 2000. The first exit meeting was held at the Ministry of Health in Rome. This meeting was held to discuss the results of the Residue Audit Team and the Laboratory Audit Team. This exit meeting was held with the FSIS personnel who conducted the residue and laboratory audits. The residue and laboratory audit teams were scheduled to leave Italy before the Inspection Program Audit was completed. Therefore, a separate exit meeting was held.

The first exit meeting was held in Rome on September 15, 2000, and was coordinated by Dr. Piergiuseppe Facelli, Direttore Ufficio III, Ministero Della Sanita, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria. The exit meeting was attended by Dr. Alessandra Di Sandro, Dirigente Veterinario I Livello, Ufficio VIII; Dr. Silvio Borrello, Direttore Ufficio VIII; Dr. Franco Fucilli, Ufficio VIII Sezione Produzione Carni Fresche; Dr. Pietro Noe, Ufficio VIII Sezione Produzione Prodotti A Base Di Carne; Dr. Carla Campagnoli, Dirigente Veterinario I Livello, Ufficio XI; MS. Annamaria Donato, Dirigente Farmacista I Livello, Ufficio XI; Dr. Agostino Macri, Dirigente del Laboratorio Veterinario, Istituto Superiore di Sanita; Dr. Patrizia Parodi, Dirigente Veterinario I Livello, Ufficio III.

The US delegation was led by Mr. Donald Smart, Director, Review Staff, Food Safety and Inspection Service (FSIS), and Dr. Faizur Choudry, Lead Auditor, International Audit Staff Officer. Also attending from FSIS were Dr. Michael Hoffman, Chemist, Laboratory Auditor; Ms. Rita Kishore, Chemist, Residue Program Auditor; Ms. Mary Stanley, Food Technologist, Residue Program Auditor; Mr. Gary Stefan, Animal Production Specialist, Residue Program Auditor; Dr. Manzoor Chaudry, Branch Chief Residue, Residue Program Auditor; Mr. Joel Salinsky, Quality Assurance Officer, Laboratory Auditor; Mr. Leon Ilnicki, Quality Assurance Officer, Laboratory Auditor; Dr. Elizabeth Leovey, Chemist, Laboratory Auditor, Environmental Protection Agency; and Mr. Clay Hamilton, Agricultural Attache, American Embassy, Rome.

The following topics were discussed:

- Audit findings and conclusions of the Laboratory Program Subgroup.
- Audit findings and conclusions of the Residue Program Subgroup.
- Investigation procedures and criminal protection of illegal veterinary drug and feed additives use in Italy.

The second exit meeting was held in Rome on September 29, 2000. At this exit meeting, the results of the Inspection Program Audit were discussed. The Italian participants were Dr. Piergiuseppe Facelli, Direttore Ufficio III, Ministero Della Sanita, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria; Dr. Angelo Donato, Ufficio III Sezione Carni E Prodottia Base Di Carne-Importazione Ed Esportazione; Dr. Silvio Borrello, Direttore Ufficio VII; Dr. Franco Fucilli, Ufficio VII Sezione Produzione Carni Fresche; Dr. Pietro Noe, Ufficio VIII Sezione Produzione Prodotti A Base Di Carne. The USDA participants were Mr. Clay Hamilton, Agricultural Attache, Foreign Agricultural Service (FAS), American Embassy, Rome; Mr. Franco Regini, Agricultural Specialist, FAS, American Embassy, Rome; and Dr. Faizur Choudry, Lead Auditor, FSIS.

The following deficiencies were discussed.

- HACCP Plans: The HACCP programs were audited and the following deficiencies with FSIS regulatory requirements were found: Identification and frequency of monitoring for CCPs; inadequate corrective actions for deviations; no HACCP plan validation; ongoing verification activities of the HACCP program; documentation of monitoring of CCPs; and the pre-shipment records review.

- SSOP Programs: The SSOP programs were audited and the following deficiencies with FSIS regulatory requirements were found: pre-operational sanitation and operational sanitation not addressed in SSOP procedures; frequency of conducting procedures; and naming of responsible individuals for the SSOP program. In the majority of establishments, GOI inspection officials were not monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation SSOP, and records were not maintained or were incomplete.

- Sanitation Controls: The following sanitation deficiencies were found: inadequate pest control programs; sanitizers not maintained at the required temperature; numerous cross contamination instances; numerous sanitation deficiencies; and several deficiencies in product handling and storage.

- Slaughter/Processing Controls: In seven establishments, the zero-tolerances for visible fecal material, ingesta, and milk on carcasses were not enforced by the GOI, and there was no monitoring record maintained to verify this activity. None of the slaughter establishments included fecal material, ingesta, and milk as a food safety hazard and did not address these hazards as critical control points in their HACCP plans. The establishments and the GOI agreed to comply with this requirement.

- Microbiology Results: The generic *E. coli* and *Salmonella* samples were being analyzed in four days in the government laboratory instead of within one day after collection. In addition, instead of using FSIS-approved methods ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella*, the laboratory was using ISO 7251 and AOAC 991.14, both of which are methods for analyzing generic *E. coli*.

- Government Oversight: In 11 establishments, supervisory visits to certified establishments were not performed monthly. In addition, government oversight of the Italian inspection program in general was inadequate.

- Residue and Laboratory Results: This information is presented in detail earlier in this report. The major deficiency is that the methodology used by the IZS's is inconsistent. Additionally, the NRL failed to provide sufficient leadership and support to the totality of the laboratory aspects of the residue control program, from performing confirmatory analyses of IZS findings to development of new methods, and coordination and oversight of laboratory data quality.

GOI meat inspection officials indicated that they would take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audits and exit meetings, would be implemented.

CONCLUSION

The Italian meat inspection system has major deficiencies, which demonstrate lack of government oversight as evidenced by the findings presented in the report and summarized below.

Nine establishments were audited: five were acceptable, two were evaluated as acceptable/re-review, and two were unacceptable. The GOI meat inspection officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance. However, these assurances have been given previously at the conclusion of the February 1998 and January 1999 audits, yet few, if any, corrective actions were taken.

The residue control program for 2000 has been implemented in the three regions visited. There are adequate controls in place to ensure compliance with residue sampling and reporting procedures. However, the significant delays in reporting results and the lack of communication from a National level compromises the effectiveness of the program.

Several major deficiencies were found in the audit of the laboratories, as well as a strong intent of IZS personnel to improve their operations. The laboratory aspects of the residue control program suffer from a lack of resources to the IZS's and a lack of oversight and coordination.

Dr. Faizur R. Choudry
International Audit Staff Officer

(Signed) *Dr. Faizur R. Choudry*

ATTACHMENTS

A. Data collection instrument for SSOP
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing.

Attachment A

Data Collection Instrument for SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the US domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respon s-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
92M/S	√	*	*	√	√	√	*	√
272M/S	√	√	*	√	√	√	*	√
312M/S	√	√	√	√	*	√	*	√
478L	√	√	*	√	√	√	*	√
515L	√	√	√	√	√	√	*	√
643M/S	√	√	√	√	√	√	√	*
768M/S	√	√	√	√	√	√	√	√
791M/S	√	√	√	√	√	*	*	√
1329M/S	√	√	*	√	√	√	√	√

√-Acceptable *-Deficiency N/A No records available

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
14L	√	*	*	√	√	√	*	√
37L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
335L	√	√	√	√	√	√	√	
350L	√	√	√	√	√	√	√	√
478L	√	√	√	√	√	√	*	√
550L	√	√	√	√	√	√	*	√
586L	√	√	√	√	√	√	*	√
596L	√	√	√	√	√	√	*	√
908L	√	√	√	√	√	√	√	√
1125L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1157L	√	*	*	√	√	√	*	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the US (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the US domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Haz. analysis – all ID'ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
92M/S	√	√	√	√	√	*	*	*	*	*	√	*
272M/S	√	√	√	√	√	*	√	√	√	√	√	√
312M/S	√	√	√	√	√	*	*	√	*	*	√	√
478L	√	√	√	√	√	√	*	*	*	√	√	*
515L	√	√	√	√	√	*	√	*	*	*	√	*

643M /S	√	√	√	√	√	*	√	*	*	√	√	*
768M /S	√	√	√	√	√	*	√	*	*	√	√	*
791M /S	√	√	√	√	√	*	*	√	*	√	√	*
1329 M/S	√	√	√	√	√	√	*	√	*	√	√	*

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
14L	√	√	√	√	√	√	√	√	√	√	√	√
37L	√	√	√	√	√	√	√	√	√	√	√	√
335L	√	√	√	√	√	√	*	√	√	√	√	√
350L	√	√	√	√	√	*	*	√	*	√	√	*
478L	√	√	√	√	√	*	*	√	*	√	√	*
550L	√	√	√	√	√	√	√	√	√	*	*	*
586L	√	√	√	√	√	*	*	√	*	√	√	*
596L	√	√	√	√	√	*	*	√	*	√	√	√
908L	√	√	√	√	√	*	*	*	*	√	√	*
1125L	√	√	√	√	√	√	√	√	*	√	√	√
1157L	√	√	√	√	√	√	*	√	*	√	√	*

√ - Accptable * - Deficiency

Data Collection Instrument for Generic *E. coli* Testing

Each establishment (except Est. 12, which was a cold-storage facility) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the US domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Writ-ten pro- cedure	2. Samp-ler des-ignated	3.Samp-ling lo-cation given	4. Pre-domin. species sampled	5. Samp-ling at the req'd freq.	6. Pro-per site or method	7. Samp-ling is random	8. Using AOAC method	9. Chart or graph of results	10. Re-sults are kept at least 1 yr
92M/S	√	√	√	√	√	√	√	√	√	√
272M/S	√	√	√	√	√	√	√	√	√	√
312M/S	√	√	√	√	√	√	√	√	√	√
643M/S	√	√	√	√	√	√	√	√	*	√
678M/S	√	√	√	√	√	√	√	√	√	√
791M/S	√	√	√	√	√	√	√	√	√	√
1329M/S	√	√	√	√	√	√	√	√	√	√
515L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
478L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Establishment 643M/S was sponging carcasses and evaluating generic *E. coli* test results using excision samples criteria. Establishment officials ordered immediate correction.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Writ-ten pro- cedure	2. Samp-ler des-ignated	3.Samp-ling lo-cation given	4. Pre-domin. species sampled	5. Samp-ling at the req'd freq.	6. Pro-per site or method	7. Samp-ling is random	8. Using AOAC method	9. Chart or graph of results	10. Re-sults are kept at least 1 yr
14L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
37L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
335L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
350L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
478L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
550L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
586L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
596L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
908L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1125L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1157L	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

NOTE: All establishments were conducting processing operations.

Data Collection Instrument for *Salmonella* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the US domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
92M/S	√	√	N/A	√	√	√
272M/S	√	√	N/A	√	√	√
312M/S	√	√	N/A	√	√	√
478L	N/A	N/A	N/A	N/A	N/A	N/A
515L	N/A	N/A	N/A	N/A	N/A	N/A
643M/S	√	√	N/A	√	√	√
768M/S	√	√	N/A	√	√	√
791M/S	√	√	N/A	√	√	√
1329M/S	√	√	N/A	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
14L	N/A	N/A	N/A	N/A	N/A	N/A
37L	N/A	N/A	N/A	N/A	N/A	N/A
335L	N/A	N/A	N/A	N/A	N/A	N/A
350L	N/A	N/A	N/A	N/A	N/A	N/A
478L	N/A	N/A	N/A	N/A	N/A	N/A
550L	N/A	N/A	N/A	N/A	N/A	N/A
586L	N/A	N/A	N/A	N/A	N/A	N/A
596L	N/A	N/A	N/A	N/A	N/A	N/A
908L	N/A	N/A	N/A	N/A	N/A	N/A
1125L	N/A	N/A	N/A	N/A	N/A	N/A
1157L	N/A	N/A	N/A	N/A	N/A	N/A

NOTE: All establishments were producing processed products only.